

**Notice of Allowability**

Application No.

10/622,516

Examiner

Delia M. Ramirez

Applicant(s)

GONG ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/4/2004.
2. ☒ The allowed claim(s) is/are 24-35.
3. ☒ The drawings filed on 21 July 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other Alignments

**DETAILED ACTION**

***Status of the Application***

Claims 24-35 are pending.

Applicant's election without traverse of Group II, claims 4-6, 8-11, and 22-23 directed to an isolated nucleic acid encoding the polypeptide of SEQ ID NO: 2, host cells and vectors in a communication filed on 6/4/2004 is acknowledged.

Applicant's cancellation of claims 1-23 and addition of claims 24-35 in a communication filed on 6/4/2004 is acknowledged. New claims 24-35 are directed to the elected invention and are being examined herein.

In a telephone conversation with Justin Karjala on 6/30/2004, an agreement was reached to amend claims 25-27 to place the claims in condition for allowance.

***Drawings***

1. The drawings filed on 7/21/2003 are accepted by the Examiner.

***Terminal Disclaimer***

2. Applicant's submission on 6/30/2004 of a terminal disclaimer to avoid a potential obviousness-type double patenting rejection of claims 24-35 over claims 1-9 of U.S. Patent No. 6436692 is acknowledged. The terminal disclaimer filed on 6/30/2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6436692 has been reviewed and is accepted. The terminal disclaimer has been recorded.

*Examiner's Amendment*

3. An informal Examiner's amendment to the specification appears below. An amendment to the title is required such that the title is clearly indicative of the invention to which the claims are directed. An amendment to the first sentence of the specification is required to add a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

4. Please enter the following amendments to the specification as follows:

5. In page 1, replace the title as follows:

"Isolated nucleic acid molecules encoding human synthase proteins, and uses thereof"

6. In page 1, immediately after the title, insert the following sentence:

This application is a divisional of U.S. Application No. 10/193,295 filed on 07/12/2002, now U.S. Patent No. 6,620,608, which is a divisional of U.S. Application No. 09/819,993 filed on 03/29/2001, now U.S. Patent No. 6,436,692.

7. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

8. Authorization for this Examiner's amendment was given in a telephone interview with Justin Karjala on 6/30/2004.

9. Please replace claims 25-27 as follows:

25. An isolated nucleic acid molecule encoding a hydroxymethylglutaryl-CoA synthase, wherein the nucleic acid molecule has a nucleotide sequence comprising SEQ ID NO: 1 or the complete complement thereof.

26. An isolated nucleic acid molecule encoding a hydroxymethylglutaryl-CoA synthase, wherein the nucleic acid molecule has a nucleotide sequence comprising nucleotides 145-1578 of SEQ ID NO: 1 or the complete complement thereof.

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27. An isolated transcript or cDNA nucleic acid molecule comprising a nucleotide sequence that encodes a hydroxymethylglutaryl-CoA synthase having an amino acid sequence comprising SEQ ID NO: 2 or the complete complement of said nucleotide sequence.

*Reasons for Allowance*

10. The following is an Examiner's statement of reasons for allowance. Although the prior art discloses nucleic acids encoding human hydroxymethylglutaryl-CoA synthases, the Examiner has found no teaching or suggestion in the prior art directed to the nucleic acid of SEQ ID NO: 1 or a nucleic acid encoding the polypeptide of SEQ ID NO: 2. The closest homolog of the protein of the instant invention is a human hydroxymethylglutaryl-CoA synthase with 98.8% sequence identity to SEQ ID NO: 2 (Rokosz et al., Archives of Biochemistry and Biophysics 312:1-13, 1994; Swiss Prot accession number Q01581; PIR accession number S45497; cited during the prosecution of parent cases 09/819,993 and 10/193,295) and the closest homolog of the nucleic acid molecule encoding the protein of the instant invention is the nucleic acid encoding the synthase of Rokosz et al., which has 68.4% sequence identity to SEQ ID NO: 1. See attached alignments. Therefore, claims 24-35 directed to nucleic acids encoding the polypeptide of SEQ ID NO: 2, host cells, vectors, and a method to recombinantly produce the polypeptide of SEQ ID NO: 2, are allowable over the prior art of record.

11. Claims 24-35 are allowed.

12. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

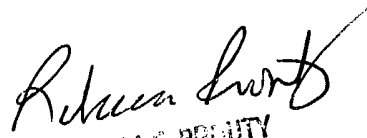
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
July 5, 2004

  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP 1800  
1652